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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

EMCH, GREGORY S

ART UNIT

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09/15/2008

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/509,841	<b>Applicant(s)</b> HYMAN ET AL.	
	<b>Examiner</b> Gregory S. Emch	<b>Art Unit</b> 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 4,7,8,13,16,17 and 19-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,6,9-12,14,15 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicants' elections of Group I, claims 1-18, of the species for Group I agents: antibodies or fragments thereof that bind to VLDL-R, and for Group II agents: antibodies or fragments thereof that bind to APP, in the reply filed on 11 June 2008 are acknowledged. Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 4, 7, 8, 13, 16, 17 and 19-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11 June 2008.

Claims 1-3, 5, 6, 9-12, 14, 15 and 18 are under examination in the instant office action.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

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are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5, 6, 9-12, 14, 15 and 18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,156,311 to Strickland et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are directed to a method for reducing catabolism of extracellular secreted amyloid  $\beta$ -precursor protein which comprises contacting a mammalian cell with an agent that

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reduces the amount or rate of binding of amyloid  $\beta$ -precursor protein (APP) with the low density lipoprotein receptor-related protein (LRP). Thus, the instant claims and the patented claims are obvious variants, since the low density lipoprotein receptor-related protein (as in the patent) is in the same receptor family as the very low density lipoprotein receptor (as in the instant claims).

Claims 1-3, 5, 6, 9-12, 14, 15 and 18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,447,775 to Strickland et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are directed to a method for reducing catabolism of full length amyloid  $\beta$ -precursor protein which comprises contacting a mammalian cell with an agent that selectively reduces the amount or rate of binding of full length APP with the LRP. Thus, the instant claims and the patented claims are obvious variants, since the low density lipoprotein receptor-related protein (as in the patent) is in the same receptor family as the very low density lipoprotein receptor (as in the instant claims).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5, 6, 9-12, 14, 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,156,311 to Strickland et al. (cited previously).

The claims are directed to a method for reducing catabolism of extracellular secreted amyloid precursor protein comprising contacting a mammalian cell with an agent that reduces the amount or rate of binding of amyloid precursor protein (APP) with the very low density lipoprotein receptor (VLDL-R).

The Strickland et al. patent teaches a method for reducing catabolism of extracellular secreted amyloid  $\beta$ -precursor protein which comprises contacting a mammalian cell with an agent that reduces the amount or rate of binding of amyloid  $\beta$ -precursor protein with the low density lipoprotein receptor-related protein (see patented claim 1), as in the instant claim 1. The patent teaches that the agent can be one that binds to APP or one that binds to LRP (see patented claims 2 and 3), as in the instant claims 2 and 11. The patent teaches that the agent can be an antibody or fragment thereof that binds to APP or LRP (see patented claims 3 and 4), as in the instant claims 3 and 12. The patent teaches that the contacting occurs *in vitro* (see patented claim 6), as in the instant claim 9. The patent teaches methods for reducing the rate of onset or the severity of Alzheimer's disease, comprising administering to an animal, such as a human, one or more Group I agents (agents which bind to the APP-binding site on the LRP particle) and/or one or more Group II agents (agents which bind to the LRP-binding site found on APP) in an amount effective to reduce the rate of APP attachment to its receptor (col.3, lines 23-26 and col.4, lines 16-21), as in the instant claims 10 and 18.

The difference between the methods disclosed in the Strickland et al. patent and those of the claimed invention is that said patent does not explicitly teach that the Group I agents include those that bind to the APP-binding site on the VLDL-R. However, upon reading the disclosure of the Strickland et al. patent, the skilled artisan would have recognized the desirability of developing additional methods of reducing the catabolism of APP and of treating Alzheimer's disease. Furthermore, the patent teaches, "it is an object of the present invention to provide agents which bind to APP or LDL-receptor

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family members and reduce the interaction, cellular internalization, and subsequent catabolism of APP" (col.3, lines 11-14) and teaches that the VLDL-R receptor is in the same receptor family as LRP, i.e. the LDL-receptor family (col.2, lines 20-25).

As evidenced by the prior art, the skilled artisan would have known that developing additional methods to decrease the catabolism of APP would be desirable. Furthermore, it would have been reasonable to predict that that an agent that binds to the APP-binding site of VLDL-R (including an antibody or fragment thereof) could be successfully used as an alternative method of reducing APP catabolism to treat Alzheimer's disease, as in claims 5, 6, 14 and 15. Thus, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to improve Strickland et al.'s methods of reducing APP catabolism to yield predictable results. This is because the artisan has good reason to pursue the known options within his or her technical grasp to obtain predictable results. Such would amount to substitution of one known equivalent for another, i.e. VLDL-R for LRP.

### ***Conclusion***

No claims are allowed.



***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached 9:00 am - 5:30 pm EST (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached at (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G.E./

Gregory S. Emch, Ph.D.  
Patent Examiner  
Art Unit 1649  
11 September 2008

/Elizabeth C. Kemmerer/  
Primary Examiner, Art Unit 1646